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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,729	10/10/2000	John D. Nguyen	3311.020US0	7128

33931 7590 11/18/2003

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EXAMINER

HOEY, ALISSA L

ART UNIT PAPER NUMBER

3765

DATE MAILED: 11/18/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/686,729

Applicant(s)

NGUYEN ET AL.

Examiner

Alissa L. Hoey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 9-14 in Paper No. 14 is acknowledged.

Double Patenting

2. Claims 9-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-14 of U.S. Application No. 10/120,579. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications provide a mitral valve repair method of providing clips that have two end points that are separated from each other when in the open configuration. The clips return to a naturally closed configuration by reducing distance between the end points. Placing an annuloplasty ring about the annulus and attaching the ring around the annulus by causing the clips to pass through the ring. The clips are attached to the ring in circumferential direction along the ring. The clips have a tissue-penetrating needle that is releasably attached through a flexible member to one of the two end points. The step of attaching the ring by causing the needle associated with each clip to penetrate and pass through the ring and tissue of the annulus. Pulling the flexible member to position and each clip so as to hold said ring to the tissue. The needle is caused to pass through the ring and tissue of the annulus and then pulling the flexible member to position so that each clip holds the ring to the tissue. The needle is caused to pass through the ring at two positions separated by a shorter distance to penetrate the tissue at one position and to come out therefrom at another position

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separated from the one position by a larger distance than said shorter distance. The clips are each generally U-shaped when in the open configuration comprising a wire of shape memory material. Each of the clips have a tissue-penetrating needle releasably attached through a flexible member to each of the two end points thereof and the step of attaching the ring comprises the steps of causing each needle of each of the clips to penetrate and come out of the annulus and to pass through the ring. Pulling the flexible members to position clips so as to hold the ring to the tissue.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 9-11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ho et al. (US 6,514,265) in view of Gilbertson et al. (US 5,064,431).

Ho et al. provides a mitral valve repair method of providing clips each having two end points which are separated from each other when in an open configuration and tending to return to a naturally closed configuration by reducing distance between the end points when in the open configuration (figures 4-8, identifiers 126, 210, 104, 138: column 3, lines 19-27 and lines 32-39). Attaching tissue and tissue or tissues and prosthesis or tissue and grafts together (figures 5 and 6, identifiers 12 and 14: column 5, lines 40-42). The clips are attached to the tissue which takes the form of an annulus to

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either the tissue or prosthesis or graft (figures 5 and 6, identifiers 121 and 210: column 12, lines 23-28). The clips have a tissue-penetrating needle releasably attached through a flexible member to one of the two end points and the step of attaching to the tissue or prosthesis or graft (figure 4, identifiers 316, 310, 318, 104, 108 and 126: column 10, lines 44-59). The needle associated with each clip penetrates and passes through the tissue of the annulus and through the tissue, prosthesis or graft connector (column 10, lines 60-67). Pulling the flexible member to position the clips so as to hold the tissue to the tissue, prosthesis or graft connector (figures 5-8, identifiers 210, 126 and 318). The clips are each generally U-shaped when in the open configuration comprising a wire of shape memory material (column 3, lines 59-60 and lines 28-31). The step of attaching the tissue, prosthesis or graft connector by causing each of the needles of each of the clips to penetrate and come out of the annulus and to pass through the tissue, prosthesis or graft connector (figure 7, identifiers 210, 12, 14 and 126).

However, Ho et al. fails to teach an annuloplasty ring being the connector in which the clips attach the tissue to and the clips being applied around the annuloplasty ring in a circumferential manner. Gilbertson et al. provides a mitral valve stenosis method using an annuloplasty ring attached to the ventricle tissue by suturing in place around the circumference (figure 1, identifiers 20, 18, 12: column 1, lines 28-49).

It would have been obvious to have provided the mitral repair method as described by Ho et al. with the annuloplasty ring connector of Gilbertson et al., since the annuloplasty ring connector is a prosthesis and could be used in the method of Ho et al. as the connector means to attach the tissue to (see Gilbertson et al. column 2, lines 5-

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12). It would have been an advantage to have provided the method of Ho et al. with the annuloplasty ring connector of Gilbertson et al., since the annuloplasty ring connector is adjustable to increase the long-term safety and effectiveness of the prosthesis.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wright et al., O'Connor, Vanney et al., Klostermeyer, Nguyen et al., Gardiner et al., Schaller et al., Gabbay and Deem et al. are all cited to show closely related medical devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alissa L. Hoey whose telephone number is (703) 308-6094. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on (703) 305-1025. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

alh


JOHN J. CALVERT
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